DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Mick Radio-Nuclear Instruments, Inc.
% Mr. Chuck Smith
Manager, Quality Assurance
521 Homestead Avenue
MOUNT VERNON NY 10550

February 19, 2015

Re: K142597
Trade/Device Name: Vienna System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: January 9, 2015
Received: January 12, 2015

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K142597

Device Name
Vienna System

Indications for Use *(Describe)*
The Nfick Radio-Nuclear Instruments, Inc. Vienna System is intended to be used as an accessory to the Nfick CT HDR Tandem / Ring Applicator and is indicated for High Dose Rate irradiation of the uterus and cervix. The Vienna System consists of perforated Build-Up Caps and complementary Needle Collectors which connect to the Nfick CT HDR Tandem / Ring Applicator. Pre-bent interstitial needles are intended to be used with the Vienna System but they are not manufactured by Nfick Radio-Nuclear Instruments, Inc. and are not part of this submission.

Build-Up Caps
When used with the CT HDR Tandem/Ring Applicator, the Vienna Build-Up Caps enable the introduction of up to nine (9) interstitial needles around the circumference of the ring to enhance the standard HDR treatment. The Vienna System is not designed to be used with any Rectal Retractor due to the introduction of the interstitial needles.

Needle Collectors
When used in conjunction with the Vienna Build-Up Caps, the Needle Collectors will maintain and control the positioning of an array of up to nine (9) interstitial needles. The Needle Collectors are part of the Vienna System ans as such, are not designed to be used with any Rectal Retractor.

The Vienna System is designed to be used as an accessory with the Applicator and this does not alter the indications for use.

Type of Use *(Select one or both, as applicable)*

[2] Prescription Use (Part 21 CFR 801 Subpart D)  O Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**Mick Radio-Nuclear Instruments, Inc.**
*An Eckert & Ziegler BEBIG Company*

521 Homestead Ave
Mount Vernon, NY 10550
USA
www.micknuclear.com

# Traditional 510(k) Summary for compliance with CFR 807.92

September 12, 2014

## 1. General Provisions

**Trade/Proprietary Name**: Vienna System.

**Common Name**: Brachytherapy Applicator

**Classification Name**: Accessory to Remote Controlled Radionuclide Applicator System (21 CFR 892.5700 – Product Code JAQ)

**Owner Name**: Mick Radio-Nuclear Instruments, Inc.
**Address**: 521 Homestead Avenue, Mount Vernon, New York 10550
**Fax**: (914) 667-3999
**Contact Name**: (914) 665-8834
Chuck Smith, Manager, Quality Assurance / Regulatory Affairs
**Contact email**: chuck@micknuclear.com

## 2. Device Name:

Vienna System

## 3. Name of Predicate Device:

The device included in this submission are substantially equivalent to the legally marketed predicate devices cited in the following table:

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521 Homestead Ave
Mount Vernon, NY 10550
USA
www.micknuclear.com

| New Device | Predicate Device | Manufacturer | K Number |
|---|---|---|---|
| Vienna System (Cat. # 0720) | CT HDR Tandem/Ring Applicator with Rectal Retractor | Mick Radio-Nuclear | K030110 |
| | HDR CT Compatible Tandem/Ring Applicator with 2 Piece Rectal Retractor | Mick Radio-Nuclear Instruments, Inc. | K122840 |
| | Nucletron Vienna Ring CT-MR Applicator | Nucletron B. V. | K080934 |

## 4. Reason for this Traditional 510(k) Premarket Notification

The purpose of this 510(k) submission is to obtain clearance to market a new device that is designed to be used with the Mick CT HDR Tandem/Ring Applicator with Rectal Retractor (Catalog # 0407). The accessories enhance the CT HDR Tandem/Ring Applicator, without changing the intended use of the applicator.

## 5. Classification

The device is classified as a class II device according to 21 CFR 892.5700.

## 6. Intended Use and Device Description

The device that is submitted for clearance in this 510(k) is intended to be used with the Mick Radio-Nuclear Instruments, Inc. CT HDR Tandem/Ring Applicator with Rectal Retractor and is intended for use in Brachytherapy. It is indicated for use where high dose rate (HDR) irradiation of the uterus and cervix is an accepted clinical practice. The applicator is designed to be compatible with the sealed sources found in High Dose Rate After-Loaders and does not modify or change the source, source packaging or remote source positioning mechanisms found on these after-loaders.

The use of the Vienna System with the CT HDR Tandem / Ring Applicator does not alter the intended use of the applicator. There are no special controls needed for this device.

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The Vienna System is comprised of two sizes of Build-Up Caps, both 5.0mm & 7.5mm, to replicate the original Build-Up Caps in the applicator set and complementary Needle Collectors. The system is designed to utilize implanted rigid interstitial needles that are commercially available and must be purchased separately. The Vienna System is not designed to be used in conjunction with any type of Rectal Retractor.

The Vienna Build-Up Caps have nine pre-drilled holes in the circumference of the Build-Up ring to accept separate interstitial needles for a wider dose distribution during treatment. One size Vienna Build- Up Cap can accommodate all three angles of Rings and Tandems.

Needle Collectors are offered as part of the system and are used to "collect", stabilize and protect interstitial needles inserted through the Vienna Build-Up Cap. The Needle Collector is offered in three different angles (30°, 45° & 60°) and all have nine channels oriented to the pre-drilled hole positions in the Vienna Build-Up Cap. The inserted needles can be clipped to the Needle Collector to provide an easy means of indexing and organizing the needles and to ensure needle stabilization at the insertion site. When used with rigid interstitial needles, it is possible to achieve asymmetric alteration of the dose distribution. Rigid interstitial needles are not supplied by Mick Radio-Nuclear Instruments, Inc. and must be purchased separately.

## 7. Drawings

Drawings of each of the components of the Vienna System are provided in Vol_9.

## 8. Manufacturing Process

The Vienna System is manufactured according to Good Manufacturing Practices (GMPs) as defined in 21CFR part 820. The processes used to fabricate these accessories are similar to those used for the predicate device described in this 510(k) notification.

## 9. Biocompatibility

No new issues of biocompatibility are raised with regard to the use of materials in manufacturing the Vienna System.

Eckert & Ziegler

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Mount Vernon, NY 10550
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## 10. Summary of Substantial Equivalence

The Vienna System is similar in design and construction, utilizes the same materials, and has the same intended use and performance characteristics of the predicate devices. The fundamental scientific technology is unchanged from the original predicate devices. No new issues of safety or effectiveness are introduced by using this device. Therefore, Performance Test Results or In vitro Testing / In vivo Testing are not applicable to the Vienna System. By introducing the Vienna Systems, no new issues of safety or effectiveness are raised.

## 11. Comparison Table

The tables below compare the individual accessory to its predicate device. tables are a comparison of the materials and intended uses of these devices.

### Vienna System (Catalog # 0720)

| **Device / Trade Name** | **CT HDR Tandem/ Ring Applicator w/ Rectal Retractor** | **Nucletron Vienna Ring CT-MR Applicator** | **HDR CT Compatible Tandem/ Ring Applicator w/ 2 Piece Rectal Retractor** | **Vienna System** |
|---|---|---|---|---|
| **K Number** | K030110 (Mick Radio Nuclear) | K080934 (Nucletron) | K122840 (Mick Radio-Nuclear) | To be determined |
| **Intended Use** | High dose rate Brachytherapy treatment of the uterus and cervix | High dose rate Brachytherapy treatment of the uterus and cervix | High dose rate Brachytherapy treatment of the uterus and cervix | High dose rate Brachytherapy treatment of the uterus and cervix |
| **Shielding** | No | No | No | No |
| **Build-Up Cap Material** | Acetal | Acetal | Acetal | Acetal |
| **Colpostat / Tandem Mat'l** | Titanium | Composite Fiber Tubing | Titanium | Titanium |
| **Needle Collector Mat'l** | N/A | N/A | N/A | PPSU |